

Vertebral augmentation by kyphoplasty in osteoporotic vertebral fractures: A clinical experience

Vertebral augmentation by kyphoplasty

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Abstract

Aim: The clinical characteristics and results of patients who underwent kyphoplasty for osteoporotic fractures in a single center between 2015 and 2023 were examined.

Material and Methods: Patients who underwent balloon kyphoplasty between 2015 and 2023 due to osteoporotic vertebral fractures were assessed. Visual Analog Scale (VAS) was used to evaluate the patients' pain before and after the clinical operation. In all fractures, local kyphosis angle and vertebral body heights were measured.

Results: A total of 103 osteoporotic vertebra fractures were treated with kyphoplasty. The patients consist of 69 females and 34 males, with a mean age of 71. The average follow-up period lasted for 9.21 ± 8.07 months. When the patients were evaluated functionally, the VAS score, which was 8.674 ± 0.46 pre-operatively, decreased to 3.019 ± 0.99 post-operatively ($p < 0.001$). Post-operative pain relief and satisfaction rate was 65.2%.

The mean local kyphosis angle, which was $19.98^\circ \pm 0.68$ pre-operatively, was found to be $18.07^\circ \pm 0.56$ post-operatively ($P < 0.001$). At the end of an average follow-up period of nine months, it was determined that there was a 1.91° improvement in post-operative local kyphosis angle. An average correction of 8.97% was achieved in terms of local kyphosis.

It was observed that an increase of 1.75 mm (8.97%) was achieved in the vertebral body restoration. Cement leakage was observed in five patients (4.85%).

Discussion: We are presenting our findings regarding the application of kyphoplasty to prevent deformity development in cases of severe pain due to osteoporotic vertebral fractures that are unresponsive to medical treatment.

Keywords

Osteoporosis, Osteoporotic Vertebral Fracture, Vertebral Augmentation, Kyphoplasty

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Introduction

In the United States, there are approximately 700,000 cases of Osteoporotic Vertebral Compression Fractures (OVCF) each year, which are a common consequence of osteoporosis. Approximately one-third of these cases are symptomatic [1, 2]. The incidence of OVCF is on the rise, primarily due to the increasing human life expectancy and the prevalence of osteoporosis. Osteoporosis is a metabolic disorder characterized by a decrease in bone mineral density, low bone mass, increased bone fragility, deterioration of bone microarchitecture, and ultimately an elevated risk of fractures [3, 4].

While the pain resulting from osteoporotic vertebral compression fractures usually subsides within three months in the majority of patients, it may become chronic due to the deformity of the spine and degeneration in the fracture area [4, 5, 6].

In recent years, percutaneous vertebroplasty and subsequently developed kyphoplasty have emerged as the most common methods for vertebral augmentation in cases of acute vertebral fracture. The primary distinction between vertebroplasty and balloon kyphoplasty, the latter being an advancement of vertebroplasty, is the goal of restoring the vertebral body to its previous height. This minimally invasive technique typically involves the injection of polymethylmethacrylate (PMMA) directly into the vertebral body through the pedicles.

Specifically, this study focuses on the clinical characteristics and outcomes of patients diagnosed with vertebral compression fractures and treated with kyphoplasty for osteoporotic fractures in our department. These findings will be discussed and presented in the context of existing medical literature.

Material and Methods

In this retrospective study, the outcomes of 103 balloon kyphoplasty procedures conducted for osteoporotic vertebral fractures between 2015 and 2023 were assessed. 15 patients underwent kyphoplasty at different time points for fractures at different levels. Among them, 11 patients underwent treatment at two vertebral levels, 3 patients received treatment at three vertebral levels, and 1 patient underwent treatment at four vertebral levels. All treated patients were diagnosed with osteoporosis and their Bone Mineral Density (BMD) value was above $T < -2.5$. Vertebral fractures secondary to non-osteoporotic causes were excluded from the study. Preoperative radiological evaluations of the cases were made with X-ray, CT, MRI (T1, T2, STIR (Short TI Inversion Recovery) sequence) and postoperative standing lateral and anteroposterior X-ray, CT. Osteoporotic compression fracture types of the patients to whom we performed kyphoplasty were included in the AO fracture classification Magerly Type A 1-2. Visual Analog Scale (VAS) was used to evaluate the patients' back pain before and after the clinical operation. In all fractures, local kyphosis angle and vertebral body heights were measured in millimeters. Follow-up evaluations were conducted at one, three and twelve months. Control radiographs were taken routinely.

During follow-up appointments, patients were examined to detect any additional fractures. The local kyphosis angle is defined as the angle between a line drawn parallel to the upper end-plate of the vertebra immediately above the fractured vertebra and the lines drawn to the lower end-plate

of the vertebra immediately below it. Body height refers to the mid-corpus height as measured on lateral radiographs. The estimated body and anterior wall heights at the fracture level were calculated by averaging the sum of the wall heights of the upper and lower levels. This analysis was conducted for all patients. The procedures were conducted using local anesthesia. Surgical procedure

Informed consents were obtained from all patients prior to the procedure. Following administration of appropriate anesthesia, the level of the fracture was determined by obtaining anteroposterior and lateral images with C-arm fluoroscopy. All patients underwent balloon kyphoplasty with an unipedicular approach. During the procedure, specimens from the collapsed vertebra were taken for pathological examination. Patients were mobilized within 6 to 24 hours following the operation. Control radiographs were taken routinely. All patients were advised to wear a brace for two weeks following the surgery.

The proportion of liquid and powder components used when preparing polymethylmethacrylate (PMMA) and the waiting time had an impact on the cement's flowability. This alteration in flowability influenced the distribution of the cement within the fractured spinal body, either positively or negatively.

Statistical Analysis

SPSS 21.0 software package (SPSS, Chicago, IL, USA) was utilized for the statistical analysis of the obtained data. Continuous data were summarized as mean \pm standard deviation, while categorical data were presented as counts and percentages. The normal distribution of continuous data was assessed using the Kolmogorov-Smirnov Test and Shapiro-Wilk Test. The comparison between preoperative and postoperative values was carried out using the Paired Samples t-test. The Chi-Square (χ^2) test was employed to examine the dependency between categorical variables for intergroup comparisons. A significance level of $p < 0.05$ was considered statistically significant.

Ethical Approval

This study was approved by Ethics Committee of Amasya University (Date: 2023-12-07, No:137-1).

Results

83 patients underwent a total of 103 kyphoplasty procedures at various time intervals. Intra-operative kyphoplasty and vertebral body correction are demonstrated in Figure 1. The distribution of fracture locations by age and gender of the patients is shown in Table 1, the comparison of fracture duration, follow-up period, preoperative pain score, postoperative pain score, preoperative local kyphosis angle, postoperative local vertebral angle, preoperative vertebral height, and postoperative vertebral height based on age (< 65 and > 65) is provided in Table 2, and the comparison of preoperative and postoperative pain scores, local vertebral angles, and vertebral body height averages is presented in Table 3. Eleven patients received treatment for two vertebral levels, while three patients were treated for three vertebral levels, and one patient underwent treatment for four vertebral levels. The average time interval between the occurrence of the fracture and the surgery was found to be 33.35 ± 14.50 days. Preoperative VAS scores were 8.674 ± 0.46 , preoperative kyphotic angle and vertebral

Table 1. Fracture segment distribution of patients according to age and gender (n=103)

Fracture segment	Age			Gender		
	<64 n (%)	>65 n (%)	Total n (%)	Female n (%)	Man n (%)	Total n (%)
T7	2 (8,0)	0 (0,0)	2 (1,9)	1 (1,4)	1 (2,9)	2 (1,9)
T8	0 (0,0)	5 (6,4)	5 (4,9)	3 (4,3)	2 (5,9)	5 (4,9)
T9	0 (0,0)	2 (2,6)	2 (1,9)	2 (2,9)	0 (0,0)	2 (1,9)
T10	0 (0,0)	3 (3,8)	3 (2,9)	1 (1,4)	2 (5,9)	3 (2,9)
T11	0 (0,0)	6 (7,7)	6 (5,8)	4 (5,8)	2 (5,9)	6 (5,8)
T12	4 (16,0)	14 (17,9)	18 (17,5)	13 (18,8)	5 (14,7)	18 (17,5)
L1	5 (20,0)	19 (24,4)	24 (23,3)	15 (21,7)	9 (26,5)	24 (23,3)
L2	4 (16,0)	11 (14,1)	15 (14,6)	10 (14,5)	5 (14,7)	15 (14,6)
L3	7 (28,0)	7 (9,0)	14 (13,6)	9 (13,0)	5 (14,7)	14 (13,6)
L4	3 (12,0)	9 (11,5)	12 (11,7)	9 (13,0)	3 (8,8)	12 (11,7)
L5	0 (0,0)	2 (2,6)	2 (1,9)	2 (2,9)	0 (0,0)	2 (1,9)
Total	25 (24,3)	78 (75,7)	103	69 (67,0)	34 (33,0)	103

X2 = 17,297 P= 0,068 X2 = 4,716 P= 0,909

Table 2. Comparison of fracture duration, follow-up period, pre-operative and post-operative pain, local kyphosis angles and vertebral heights according to age (<65 and >65)

	<65		>65		P
	Mean	Std. Error Mean	Mean	Std. Error Mean	
Fracture duration (days)	32.40	3.29	33.65	1.57	0.709
Follow-up period (months)	9.52	1.66	9.12	0.91	0.829
Pre-operative VAS	8.62	0.97	8.69	0.52	0.510
Post-operative VAS	3.2	2.30	3.1	1.10	0.997
Pre-operative kyphosis angle	19.64	1.37	21.18	0.71	0.002
Post-operative kyphosis angle	16.22	1.24	18.72	0.59	0.046
Pre-operative vertebra body height	19.35	1.1	19.58	0.45	0.816
Post-operative vertebra body height	21.99	0.95	21.00	0.51	0.325

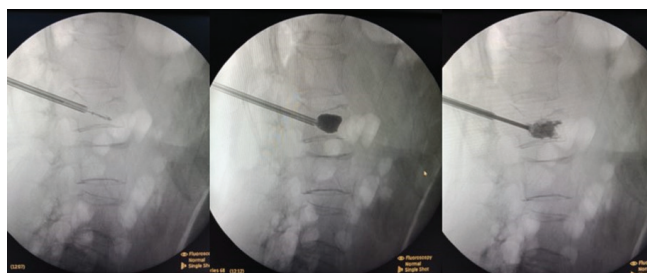


Figure 1. Intra-operative Kyphoplasty and demonstration of vertebral body correction

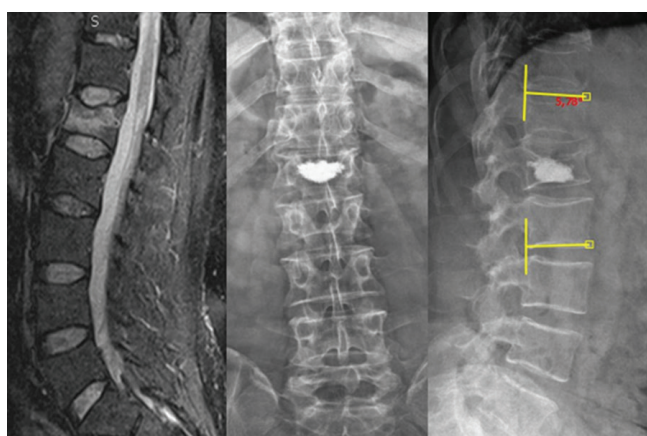


Figure 2. The preoperative MRI (STIR sequence) of the L1 vertebra fracture, postoperative radiographs and the measurement image of the local kyphosis angle

Table 3. Comparison of the mean preoperative and postoperative pain scores, local kyphosis angles, and heights.

	n	Pre-operative	Post-operative	P
		$\bar{X} \pm S_{\bar{x}}$	$\bar{X} \pm S_{\bar{x}}$	
VAS	103	8.674 ± 0.46	3.019 ± 0.99	0.001
Local kyphosis angle	103	19.98 ± 0.68	18.07 ± 0.56	0.001
Vertebral body height	103	19.49 ± 0.43	21.27 ± 0.45	0.001

body height were $19.98^{\circ} \pm 0.68$ and 19.49 ± 0.43 respectively ($P<0.001$).

An average of 3.05 ± 0.83 ml of cement was used for balloon kyphoplasty. Cement leakage was observed in five patients (4.85%). The VAS score, which was 8.67 ± 0.46 pre-operatively, decreased to 3.01 ± 0.99 post-operatively ($p<0.001$). Post-operative pain relief and satisfaction rate was 65.2%. The postoperative mean local kyphosis angle and vertebral height were $18.07^{\circ} \pm 0.56$ and 21.27 ± 0.45 respectively ($P<0.001$).

It was observed that in two cases the cement was extravasated from the cannula path in the pedicle to the posterior, in two cases the cement was extravasated to the anterior of the vertebra corpus, and in one case it was extravasated to the upper disc space due to the broken end-plate.

No statistically significant association was observed between the vertebral fracture segment and age or gender ($P>0.05$). However, upon examination of Table 1, it was noted that

fractures were more prevalent in individuals aged 65 and over, as well as in females, across all spinal levels. Moreover, the most common fractured levels were L1 and T12 vertebrae, followed by L2 and L3 levels (Table 1).

The distribution of fractures by vertebral segments was as follows: two at T7 (1.9%), five at T8 (4.9%), two at T9 (1.9%), three at T10 (2.9%), six at T11 (5.8%), eighteen at T12 (17.5%), twenty-four at L1 (23.3%), fifteen at L2 (14.6%), fourteen at L3 (13.6%), twelve at L4 (11.7%), and two at L5 (1.9%). The distribution of patients' gender and fracture segments by age groups is presented in Table 1.

Comparison of fracture duration, follow-up period, preoperative and postoperative pain, local kyphosis angles and vertebral heights according to age is given in Table 2. The preoperative local vertebral angle differed significantly between age groups, with a mean of 19.64 degrees for those below 65 years and 21.18 degrees for those aged 65 or above ($P < 0.01$). The average post-operative angle correction was measured as 16.22 in those under 65 years of age and 18.72 in those over 65 years of age, and it was found to be statistically significant ($P < 0.05$). No statistically significant difference was observed between the averages of those under and over 65 years of age in other variables ($P > 0.05$). When the patients were evaluated functionally, the VAS score, which was 8.67 ± 0.46 pre-operatively, decreased to 3.01 ± 0.99 post-operatively ($P < 0.001$). Post-operative pain relief and satisfaction rate was 65.2%. The average follow-up period lasted for 9 months. The mean local kyphosis angle, which was $19.98^\circ \pm 0.68$ pre-operatively, was found to be $18.07^\circ \pm 0.56$ post-operatively ($P < 0.001$). At the end of an average follow-up period of nine months, it was determined that there was a 1.91° improvement in postoperative local kyphosis angle (Table 3). An average correction of 8.97% was achieved in terms of local kyphosis angle.

The preoperative MRI (STIR sequence) of the L1 vertebra fracture, postoperative radiographs and the measurement image of the local kyphosis angle are presented in Figure 2.

It was noted that the height of the posterior wall of the vertebra was within the normal range for all patients. The primary collapse occurred in the middle of the vertebral body and the anterior vertebral wall. When compared to pre-operative values, it was determined that the vertebral body height increased from 19.49 ± 0.43 mm to 21.27 ± 0.45 mm. ($P < 0.001$). It was observed that an increase of 1.75 mm (8.97%) was achieved in the vertebral body restoration.

None of the patients who underwent percutaneous kyphoplasty experienced any neurological or systemic complications. Osteomyelitis and adjacent superficial tissue infection did not develop in any of our cases. No new fracture was observed in the control radiographs.

Discussion

Conservative treatment is often insufficient for many patients. None of these treatment methods are aimed at addressing vertebral deformation, which has been shown to significantly improve overall quality of life, patient mobility, lung function, bone metabolism, and the ability to return to daily life as quickly as possible. It leads to a decrease in functional independence

and chronic pain, causing significant morbidity. Additionally, inadequate vertebral height, the sequelae of spinal deformities, decreased mobility, and reduced quality of life emphasize the importance of surgical correction [5,6,7].

Balloon kyphoplasty and vertebroplasty have been found to be beneficial for restoring bone height in chronic back pain resistant to traditional treatments. Vertebral augmentation can at least prevent future vertebral collapse and further deformity. There are valid hopes that its long-term effects may be better than conservative treatment [6]. We evaluated our clinical experience, pain relief, complications added during the follow-up period, and our vertebral correction results in the light of the literature.

In the literature, we mostly see studies comparing the vertebral augmentation process with traditional methods and evaluating the average level of pain relief [7,8,9]. In addition to treating pain, the aim should be to use preventive treatment methods to ensure vertebral restoration as soon as possible and to protect against complications and deformities that may develop.

Percutaneous kyphoplasty, which represents a more advanced form of vertebroplasty, yields favorable outcomes by promptly alleviating pain and ensuring early vertebral stabilization. Kyphoplasty aims to restore the previous angle and height of the spine.

Peter et al. findings regarding the effectiveness of vertebral augmentation in reducing pain compared to traditional treatment. The vertebral augmentation group was more effective in reducing pain in the first month compared to the traditional treatment group. The difference in mean pain level between the two groups was in favor of the vertebral augmentation group. Similar results were observed at other time periods, one to two weeks and one year. However, there was significant statistical heterogeneity in the data combining pain analyses. Specifically, based on data from one study at 24 months, there was no significant difference in mean pain level between the vertebral augmentation group and the conventional treatment group [10]. In our study, there was a statistically significant difference in the averages of pain scores, vertebral correction angles, and vertebral body restoration between preoperative and postoperative measurements ($P < 0.001$).

Steinmann et al. conducted a superiority study looking at unipedicular and bipedicular kyphoplasty and showed that the two approaches are similar when it comes to the restoration of the mechanical integrity of vertebra, but because the unipedicular approach provides reduced vertebral pedicle cannulation risk, operative time, radiation exposure, and even cost, it would be the advisable approach [11]. Due to these reasons and advantages, kyphoplasty is performed unipedicularly in our clinic.

A study by Wang et al. concluded that 98% of patients experienced pain relief 24 hours after surgery and that there was a demonstrated increase in mobility associated with surgical intervention [12].

Another study of 300 patients (149 kyphoplasty and 151 nonsurgical) determined that balloon kyphoplasty was more beneficial than nonsurgical therapy. Kyphoplasty improved patients' quality of life and mobility and reduced pain, all without increasing the chances of another fracture occurring

in adjacent vertebra [13]. In our study, the VAS score decreased to 3.01 at postoperative control. Post-operative pain relief and satisfaction rate was 65.2%. No fracture developed in the adjacent segment in any of our patients.

In a study based on clinical experience by Lemke et al. regarding the treatment of painful osteoporotic compression fractures, they claimed that both vertebroplasty and kyphoplasty can reduce pain and improve quality of life. However, they claimed that kyphoplasty provided better mobility and restored some of the deformities and height of the vertebral body [14]. However, in our study, we do not claim to restore the vertebral local kyphosis angle. The average local kyphosis angle, which was 19.98° degrees before kyphoplasty, decreased to 18.07° degrees afterwards. It is seen that an average of 1.91% improvement was achieved in terms of local kyphosis.

A retrospective study conducted by Tolba et al. investigated the advantages of kyphoplasty. The study revealed that this procedure leads to a significant increase in vertebral height, approximately 42%, while also enhancing overall function and reducing both pain and the necessity for opioid analgesics [15]. Within the case series we have included in our study, it was observed that the posterior wall height remained within the normal range. The primary collapse occurred in the anterior wall and middle vertebral body. In a comparison with preoperative measurements, it was evident that the vertebral height increased from 19.52 mm to 21.27 mm, signifying an improvement of 1.75 mm (8.97%). Similar results were also obtained by Zarate et al. who observed a reduction in pain for the full 2-year follow-up [16].

In our case series, no cement leakage into the vertebral venous system was observed. In 5 cases, cement leakage developed in the front and back of the vertebral body, disc space and cannula entry area. A common concern and source of adverse reactions in all vertebral augmentation procedures is cement leakage from the vertebral bodies into the venous system. More precise control of cement flow is necessary. Osteomyelitis and adjacent superficial tissue infection did not develop in any of our cases. In a cadaveric study, Lador et al. also reports that vertebral augmentation through high-viscosity cement produces less severe extravasation compared to standard cements [17].

Genev et al. propose the necessity of identifying potential new biomarkers to assess the efficacy of treatment strategies for spinal compression fractures. They also emphasize the importance of conducting prospective clinical studies [18].

Furthermore, it is crucial to establish a standardized approach for evaluating and measuring the effectiveness of kyphoplasty. Specifically, our clinical recommendation is that kyphoplasty should be undertaken within a timeframe of 5 to 14 days following the onset of the fracture [19]. Performing the procedure within this window is essential because initiating it earlier than 5 days may carry an increased risk of infection due to the heightened inflammatory response during the acute phase. Conversely, delaying the procedure beyond 14 days significantly reduces the likelihood of successful vertebral height restoration.

Conclusion

Kyphoplasty is safe and an effective procedure for alleviating pain and improving function in patients with appropriate

indications. This approach offers the advantages of being percutaneous, involving minor surgery, and having a low complication rate. It is a preferred treatment method in suitable patients with appropriate indications due to its ease of percutaneous application. Additionally, it provides early mobilization and high patient satisfaction, particularly in cases of acute pain.

Scientific Responsibility Statement

The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Animal and Human Rights Statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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Conflict of Interest

The authors declare that there is no conflict of interest.

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